

CHARGE: Between 8-3-59 and 10-2-59, *Nembutal Sodium capsules* were dispensed 3 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 3-20-61. \$450 fine.

6539. (F.D.C. No. 45222. S. Nos. 40-361/2 R, 40-721 R, 40-723/6 R, 40-823 R.)

INFORMATION FILED: 4-27-61, E. Dist. Mo., against John F. Hendricks, t/a Hendricks Drug Store, Memphis, Mo.

CHARGE: Between 4-29-60 and 5-12-60, *Chloromycetin capsules* were dispensed 3 times, *Meticorten tablets* were dispensed 3 times, and *Nembutal Sodium capsules* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 5-22-61. \$450 fine, plus costs.

6540. (F.D.C. No. 45201. S. Nos. 13-148/9 P, 13-151/6 P.)

INFORMATION FILED: 4-7-61, E. Dist. Mich., against Sussex Pharmacy (a partnership), Warren, Mich., and Lewis Kahn and William Burk (partners in the partnership).

CHARGE: Between 12-12-59 and 12-21-59, *Achromycin capsules* (counts 1, 2, and 5) were dispensed 3 times; *dextro-amphetamine sulfate capsules* (counts 3 and 8) and *dextro-amphetamine sulfate tablets* (counts 4 and 6) were each dispensed twice; and *penicillin G potassium tablets* (count 7) were dispensed once without a prescription.

PLEA: Guilty by the partnership to all 8 counts of the information; by Burk to counts 3, 4, 5, 6, 7, and 8; and by Kahn to counts 1, 2, 3, 5, 6, and 7.

DISPOSITION: 5-17-61. Partnership fined \$400; each individual fined \$600.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 6501 TO 6540

PRODUCTS

	N.J. No.		N.J. No.
Achromycin capsules.....	6540	Diphetamine tablets.....	6536
AM Plus capsules.....	6537	Equanil tablets.....	6525, 6529
Amphetamine, dextro-, sulfate capsules.....	6518, 6540	Medrol tablets.....	6535
tablets.....	6507, 6511, 6514-6517, 6519, 6540	Meticorten tablets.....	6539
sulfate tablets.....	6501- ¹ 6513, ¹ 6522, 6527, 6528, ¹ 6532	Miltown tablets.....	6519, 6524, 6535
Chloromycetin capsules.....	6533, 6539	Nembutal Sodium capsules.....	¹ 6521, ¹ 6522, 6538, 6539
Decadron tablets.....	6533	Penicillin G potassium tablets..	6531, ¹ 6534, 6540
Desoxyephedrine hydrochloride tablets..	6507, 6508, 6511, 6526, 6527	Pentobarbital sodium capsules..	¹ 6522, ¹ 6532
Dexamyl tablets.....	6510, ¹ 6520	Prednisone tablets.....	¹ 6534
Dexedrine Spansule capsules....	6506	Preludin tablets.....	6535
Sulfate tablets.....	¹ 6520-6525	Secobarbital sodium capsules....	¹ 6520, 6528, 6529, 6534
Dextro-amphetamine sulfate capsules.....	6518, 6540	Seconal Sodium capsules.....	6519, ¹ 6521, 6525, 6530
sulfate tablets.....	6507, 6511, 6514-6517, 6519, 6540	Thyroid tablets.....	6535
		Tuinal capsules.....	6530, ¹ 6532

¹ (6513, 6520, 6521, 6522, 6532, 6534.) Prosecution contested.

U.S. Department of Health, Education, and Welfare**FOOD AND DRUG ADMINISTRATION****NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD,
DRUG, AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]
6541-6580

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent, or in one case each, after trial by the court or motion for summary judgment; (2) criminal proceedings which were terminated upon pleas of guilty and upon a judgment of guilty after trial; (3) a contempt proceeding for violation of an injunction which was terminated upon a plea of guilty; and (4) injunction proceedings terminated upon the entry of a permanent injunction by consent, and upon the entry of a permanent injunction following the reversal by the appellate court of the judgment of the trial court. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs*.

WASHINGTON, D.C., June 4, 1962.

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*For presence of a habit-forming substance without warning statements, see Nos. 6546, 6548; omission of, or unsatisfactory, ingredients statements, Nos. 6546, 6548; an imitation of another drug, No. 6574; failure to bear a label containing an accurate statement of the quantity of the contents, No. 6548; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 6548; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 6558.

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D.D.N.J. NOS. 6541-6580**

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(c), a word, statement, or other information required by, or under authority of, the Act to appear on the label or labeling of the article was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(d), the article was for use by man and contained a quantity of peyote or other named narcotic or hypnotic substance, or a chemical derivative of such substance, which derivative had been by regulations designated as habit forming, and its label failed to bear the name, and quantity or proportion of such substance or derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i) (2), the article was an imitation of another drug; Section 502(l), the article was composed wholly or in part of a kind of penicillin, or streptomycin, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b) (4), the article was a drug subject to Section 503(b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6541. Dexules timed disintegration capsules. (F.D.C. No. 44602. S. No. 8-880 R.)

QUANTITY: 6 display ctns., containing 12 btls. each, at Buffalo, N.Y.

SHIPPED: 4-15-60, from Hoboken, N.J.

LABEL IN PART: (Btl.) "30 Timed Disintegration Dexules All Day Appetite Suppressant * * * Approved Pharmaceutical Corp. Syracuse * * * New York